REMARKS

Claims 1-4 are pending.

I. Amendments to the specification

The first paragraph of the specification has been amended to recite that the instant "application for U.S. patent is a U.S.C., Title 35, §111(a) application, which is a continuation-in-part of U.S. Patent Application, Serial No. 08/814,974 filed March 6, 1997 (now Pat. No. 6,129,930), which is a continuation-in-part of application Serial No. 08/368,378 filed January 14, 1995 (now Pat. No. 6,080,428), which is a continuation-in-part of application Serial No. 08/124,292 filed September 20, 1993 (abandoned)."

The paragraphs beginning at page 3, line 25 and page 44, line 1 have been amended to correct typographical errors. The table beginning at page 42, line 1 has been amended to correct typographical errors.

No new matter has been added by these amendments.

II. Amendments to Figure 5

Replacement Figure 5 is submitted herewith to correct typographical errors. Specifically, the third bar from the left has been amended to recite "32.7%" instead of "37.9%" and the fourth bar from the left has been amended to recite "67.3%" instead of "62.1%." No new matter is added by these amendments.

III. Claim rejections for anticipation under 35 U.S.C. § 102(e)

A. Claims 1-4 have been rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,406,715

Claims 1-4 have been rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,406,715.

The '715 patent and the instant application share the same lineage, i.e., both are continuation-in-part applications of Serial No. 08/814,974, filed March 6, 1997 (now U.S. Pat. No.

6,129,930), which is a continuation-in-part of Serial No. 08/368,378, filed January 14, 1995 (now U.S. Pat. No. 6,080,428), which is a continuation-in-part of Serial No. 08/124,392, filed September 20, 1993 (abandoned).

The specification has been amended to claim priority back to September 20, 1993, the filing date of the great grandparent application (Serial No. 08/124,292). 37 CFR § 1.78 provides time limits for claiming the benefit of earlier filed applications, but these limits only apply to applications filed on or after November 29, 2000. See 37 CFR § 1.78(a)(2)(ii). The instant application was filed October 31, 1997. Accordingly, the time limits under Rule 78 do not apply to the instant application. Thus, with this amendment, the '715 patent and the instant application have the same effective filing date, removing the '715 patent as a 35 U.S.C. § 102(e) reference. Accordingly, this rejection should be withdrawn.

B. Claims 1-4 have been rejected as anticipated by U.S. Patent No. 6,129,930 under 35 U.S.C. § 102(e).

As amended, the instant application and the '930 patent both claim the benefit of the 08/124,392 application filing date, September 20, 1993. Section 102(e) states that a "person shall be entitled to a patent unless the invention was described in a patent granted on an application for patent by another ... before the invention by the applicant for patent." Accordingly, the '930 patent is not a prior art reference under 35 U.S.C. § 102(e) and this rejection should be withdrawn.

IV. Claim rejections under 35 U.S.C. § 101 for statutory double patenting

A. Claims 1-4 have been rejected under 35 U.S.C. § 101 for claiming the same invention as claims 1-17 and 34-132 of U.S. Patent No. 6,129,930

According to the Examiner, the "instant claims are directed toward an intermediate release formulation, however the structural components of the formulation in both the patent '930 and the instant disclosure are identical. Thus the composition of the patent and the instant claims is the same" (Office Action, page 6).

A claim should not be limited to a preferred embodiment disclosed in the specification. See *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 865 (Fed. Cir. 1988) ("References

to a preferred embodiment, such as those often present in a specification, are not claim limitations."). Thus, disclosure of the same formulation in the '930 patent and the instant application does not limit the claims of either to that embodiment.

"'Same invention' means identical subject matter." MPEP 804 (citing *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1984)). Contrary to the Examiner, because a species can be encompassed by two genera, it does not necessarily follow that the genera are identical.[1] For example, a red ball is a species encompassed by the genus "red things" and the genus "balls." Claims directed to (1) red things and (2) balls do not encompass identical subject matter. '930 claims 1-17, 34-53 and 57-132 are directed to methods for administering nicotinic acid during the evening at night. '930 claims 54-56 are directed to methods for administering nicotinic acid tablets. The instant claims 1-4 are directed to methods of administering intermediate release nicotinic acid formulations, which do not include a time of day or specific dosage form limitation. Thus, while the instant claims and the '930 claims can encompass some of the same species of niacin formulations, they are not directed to identical genera of niacin formulations. Accordingly, this rejection should be withdrawn.

B. Claims 1-4 have been rejected under 35 U.S.C. § 101 for claiming the same invention as claims 1-27 of U.S. Patent No. 6,676,967

According to the Examiner, "Table 1B [of the '967 patent] discloses the same exact ingredients as are disclosed in the instant application's Table 1B. Thus the method of administering the same composition makes the scope of the instant and patented claims identical, and thus this constitutes statutory double patenting" (Office Action, page 7). Claims directed to a genus of formulations having certain characteristics (e.g., an *in vivo* absorption profile) do not encompass identical subject matter as claims directed to a genus of formulations having certain other characteristics (e.g., an *in vitro* dissolution profile) because one particular formulation is encompassed by both sets of claims. See Section IV(A), above. Accordingly, this rejection should be withdrawn.

[1] "It is noted that that [sic] instant claims are directed toward an intermediate release formulation, however the structural components of the formulation in both the '930 and the instant disclosure are identical. Thus the composition of the patent and the instant claims is the same" (Office Action, page 6).

V. Provisional rejections of claims 1-4 for obviousness-type double patenting over claims 1-148 of U.S. Patent No. 6,129,930; claims 1-16 of U.S. Patent No. 6,406,715; and claims 1-16 of U.S. Patent No. 6,746,691

Claims 1-4 have been provisionally rejected for obviousness-type double patenting over (1) claims 1-148 of U.S. Patent No. 6,129,930; (2) claims 1-16 of U.S. Patent No. 6,406,715; and (3) claims 1-16 of U.S. Patent No. 6,746,691. Applicant defers responding to these provisional rejections until allowable subject matter has been identified.

VI. Claims 1-4 have been rejected under 35 U.S.C. § 112, first paragraph, enablement

Claims 1-4 have been rejected under 35 U.S.C. § 112, first paragraph, enablement. According to the Examiner, the specification does not enable polymers other than hydroxypropylmethylcellusose (HPMC): "formulation[s] comprising polymers not specifically disclosed in ranges and amounts outside the ranges disclosed in the specification are not enabled" (Office Action, page 10).

Methods for making sustained release niacin formulations were well known in the art. See, e.g., specification, page 3, lines 4-12 and page 4, lines 10-21. Polymers, other than HPMC, for use as swelling agents to provide sustained release were also well known. Examples of suitable polymers disclosed in the specification include sodium carboxymethylcellulose and methylcellulose (specification, page 24, lines 17-18). Other disclosed swelling agents include waxes such as bees wax and natural materials such as gums or gelatins (specification, page 24, lines 17-19).

The instant specification and claims provide what was not known, i.e., an absorption profile for a niacin formulation that is "just right" such that hyperlipidemia is effectively treated and hepatotoxicity is avoided. See, e.g., specification page 5, line 25 to page 8, line 2; page 9, lines 20-27; Figure 3. Such a sustained release niacin formulation is termed "intermediate release" in the instant specification. See, e.g., specification, page 7, lines 15-23; page 14, lines 18-20. Having knowledge of this profile, it is a matter of routine experimentation for one of ordinary skill in the art to select other polymers (for example, polymers used in prior art sustained release niacin formulations or disclosed in the specification) in suitable amounts, which will provide the claimed

absorption profile. "As is known in the art, such swelling agents and amounts thereof, may be preselected in order to control the time release of the active ingredient" (specification, page 24, lines 16-17). See also, specification, page 24, lines 19-22. Accordingly, this rejection should be withdrawn.

Conclusion

No new matter has been added. In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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